K032748 OCT 2 9 2003

Attachment 1 - 510(k) Summary

Submitter's Name / Contact Person

Stephen S. Andersen
Sr. Director of Quality and Customer Satisfaction
Vital Images, Inc.
3300 Fernbrook Lane N, Suite 200
Plymouth, MN 55447

General Information

Trade Name	Vitrea2, Version 3.4 Medical Image Processing Software
Common / Usual Name	System, Image Processing, Radiological
Classification Name	LLZ, Class II, CFR 21 892.2050
Predicate Devices	Vital Images, Inc., Vitrea2, Version 2.1 (K002519) GE, Advantage Workstation 4.1 (K020483) R2 Technologies, Inc., ImageChecker-CT Workstation (K023003) GE, Advanced Lung Analysis (K013381)

Device Description

Vitrea™2 is a medical diagnostic workstation that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea™2, version 3.4 is an upgrade to Vitrea™2, version 2.1 initially released for commercial distribution by FDA on K002519.

Vitrea® 2 provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The Vitrea2 user interface follows typical clinical workflow patterns to process, review, and analyze digital images, including:

- Retrieve image data over the network via DICOM
- Display images that are automatically adapted to exam type via dedicated protocols
- Select images for closer examination from a gallery of up to six 2D or 3D views
- Interactively manipulate an image in real-time to visualize anatomy and pathology
- Annotate, tag, measure, and record selected views
- Output selected views to standard film or paper printers, or post a report to an Intranet Web server or export views to another DICOM device
- Retrieve reports that are archived on a Web server

Intended Use

Vitrea™2, Version 3.4 is a medical diagnostic workstation that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. In addition, Vitrea™2 has the following specific indications.

VScore™ (K990442) is an option within the Vitrea™2 application and is intended for cardiac scoring from whole body CT derived measurements, including non-invasive detection and quantification of atherosclerotic plaque. Two image processing options, **EKG Gate** (K001682) and **Auto Gate** (K003230), allow the operator to select images with reduced motion artifacts when processing data for Coronary Artery Calcification Scoring.

Automated Vascular Measurement (K002519) is an option within the Vitrea™2 application and is intended for study/analysis of selected vessels for stenosis analysis, pre/post stent planning and directional vessel tortuosity evaluation.

Tumor Volume Measurement (K002519) is an option within the Vitrea™2 application and is intended for the analysis/quantification of tumor volumes obtained from MR brain series scans.

CT Brain Perfusion (K003639) is an option within the Vitrea™2 application and is intended for post processing based on dynamic CT images continuously acquired during the injection of contrast for the visualization of apparent blood flow in brain tissue and pictorial illustration of perfusion related parameters to aid in the assessment of the type and extent of cerebral perfusion disturbances.

ImageCheckerCT is an option within the Vitrea™2 application and is intended for the display of a composite view of 2D cross-sections, and 3D volumes of Chest CT images, including findings of regions of interest ("ROI") identified by the radiologist, or Computer Assisted Detection ("CAD") findings.

Predicate Device Comparison

The Vitrea2, Version 3.4 Workstation and the predicate devices allow for the analysis, communication and media interchange of digital images acquired from a variety of acquisition devices. All devices support the DICOM protocol for communication of images with other medical imaging devices.

Summary of Studies

The software utilized was designed, developed, tested, and validated according to written Design Control procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validating and maintenance.

The Vitrea2, Version 3.4 Workstation will successfully complete Integration testing/verification prior to Beta validation. The software Beta testing validating the workstation will be successfully completed prior to release. In addition, potential hazards have been studied and controlled by a Risk Management Plan.

Conclusion

The Vitrea2, Version 3.4 Workstation has the same intended use as the predicate devices and very similar indications and technological characteristics. Any technological differences do not raise any new questions regarding safety or effectiveness. Thus, the Vitrea2, Version 3.4 Workstation is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2003

Mr. Stephen S. Anderson
Sr. Director, Quality
and Customer Satisfaction
Vital Images, Inc.
3300 Fernbrook Lane North, Suite 200
PLYMOUTH MN 55447-5341

Re: K032748
Trade/Device Name: Vitrea2, Version 3.4
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 4, 2003
Received: September 5, 2003

Dear Mr. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032748

Device Name: Vitrea™2, Version 3.4 Medical Image Processing Software

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David B. Eggum

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032748